UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF SUSAN BAIN

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INTRODUCTION

Dr. Susan Bain seeks to opine that Zhejiang-Huahai Pharmaceuticals Ltd. ("ZHP") violated current Good Manufacturing Practices ("cGMPs") in large part because it should have known that two different complex manufacturing processes had the potential to generate nitrosamines years before the U.S. Food and Drug Administration ("FDA") provided any guidance regarding the testing for such compounds. As Dr. Bain's deposition testimony makes clear, she has no relevant expertise on these matters; she misrepresented the extent of her regulatory experience on her resume; she does not comprehend basic concepts necessary to address these specialized subjects; and she offers bottom-line legal conclusions and repackaged opinions of other experts that contravene *Daubert* and Rule 702. Accordingly, all of her opinions should be excluded from trial.

First, Dr. Bain has no relevant experience or knowledge regarding Active Pharmaceutical Ingredient ("API") manufacturers, much less the regulatory scheme that governs those companies. Rather, the vast majority of Dr. Bain's regulatory experience involves consulting with medical device companies, with the remainder consisting of a brief stint at the FDA early in her career, where she worked at a junior level on medical device issues and, to a lesser extent, veterinary drugs. None of this experience is relevant to the regulatory requirements applicable to API manufacturers. Nor does Dr. Bain's private sector experience –

which included a couple of years at Watson Pharmaceuticals ("Watson"), a generic pharmaceutical manufacturer – suffice, as Dr. Bain misrepresented the extent of this and virtually all of her purportedly "FDA-related" private-sector experience on her resume. Contrary to what is represented on her resume, Dr. Bain admitted at her deposition that she has ***not*** responded to 483 or warning letters from the FDA; she has ***not*** communicated with the FDA about product recalls; and all she could recall in her entire career was ***three*** calls with the FDA, lasting less than ***30 minutes*** in total. It is thus no surprise that Dr. Bain was unable to answer even the most basic questions about the very regulatory scheme that supposedly underlies her opinions and the requirements she claims ZHP violated.

Second, Dr. Bain is not qualified to opine on the two manufacturing processes discussed in her report – i.e., the TEA with sodium nitrite quenching process and the zinc chloride process. As Dr. Bain repeatedly conceded, she is not an organic chemist, which is presumably why she was unable to answer basic questions at her deposition about these processes (she could not even differentiate the two), much less competently discuss the testing that her report asserts ZHP should have conducted with respect to those processes. It also explains why the closest Dr. Bain came to defending these opinions was to repeatedly assert that they are supported by the conclusions of plaintiffs' other experts – Drs. Ron Najafi and Stephen Hecht – which Dr. Bain admitted she did not, and was not even

qualified to, independently verify. Such parroting cannot compensate for Dr. Bain's utter lack of expertise; rather, it confirms that she is not qualified to offer any science-based opinions in this case.

Third, even if Dr. Bain were qualified to testify about ***any*** of the regulatory or science-based topics discussed in her report, her opinions would still be inadmissible because they are not based on any discernible – much less reliable – methodology (e.g., Dr. Bain admitted that she only considered documents handpicked by plaintiffs' counsel); they largely boil down to improper legal conclusions (e.g., that ZHP violated the Food, Drug and Cosmetic Act ("FDCA")) of the sort that this Court has previously excluded; and they consist of summaries of fact deposition testimony that jurors can understand for themselves without the subjective gloss of an "expert," particularly one who lacks any relevant expertise.

For all of these reasons, discussed in greater detail below, the Court should exclude Dr. Bain's opinions in full.

BACKGROUND

Dr. Bain seeks to offer opinions "with regard to the manufacturing and sale of [V]alsartan API by ZHP that resulted in nitrosamine impurities NDMA and NDEA in the [V]alsartan API manufactured with the TEA with sodium nitrite quenching and zinc chloride processes" as well as "the manufacture by ZHP of Valsartan finished dose incorporating that API." (Report of Susan Bain ("Bain

Rep.") at 1 (Ex. 1 to the Certification of Jessica Davidson ("Davidson Cert.")).) More specifically, Dr. Bain states that defendant ZHP's manufacture of the Valsartan API "violated [c]GMPs" pursuant to federal regulations and related guidance documents. (*Id.*) Additionally, Dr. Bain devotes a significant portion of her report to detailing the two manufacturing processes at issue – the TEA with sodium nitrite quenching process and zinc chloride process (*see, e.g., id.* at 19-24) – and asserting that ZHP violated cGMPs in connection with both of those processes (*see, e.g., id.* at 69-74). Despite offering these opinions, Dr. Bain has no experience in the fields of either API manufacturing regulations or organic chemistry.

During her brief tenure at the FDA, Dr. Bain worked in a junior capacity as a "Consumer Safety Officer" from 2002-2003. (*See id.* at 2; *see also* Dep. of Susan Bain ("Bain Dep.") 13:17-14:10, 113:20-114:4, Jan. 31, 2023 (Ex. 2 to Davidson Cert.).) In that position, Dr. Bain spent about "60 percent" or "70 percent" of her time working with medical device manufacturers and the remainder in "veterinary drugs." (Bain Dep. 14:25-15:19.) Dr. Bain never worked on human pharmaceuticals at the FDA (*see id.* 16:1-3) and was "not trained on APIs" (*id.* 120:3-11). Dr. Bain also "never "evaluate[d] [c]GMP compliance by manufacturers of finished drug products for humans" (*id.* 114:5-8), never conducted "any inspections of API manufacturers" (*id.* 113:20-25; *see also id.*

16:9-11) and never reviewed a Drug Master File (*see id.* 16:4-6) or an Abbreviated New Drug Application ("ANDA") (*see id.* 16:7-8).

Dr. Bain's consulting work with InCompliance Solutions, where she currently works as a sole proprietor (*see id.* 47:15-21), also has not involved any work with "API manufacturers" (*id.* 226:25-227:4). Instead, "about 70 percent of [her] clients have been medical device" manufacturers, with the remainder being non-API "drug or biologic manufacturers." (*Id.* 226:16-227:2.) Similarly, although Dr. Bain is an "Assistant Professor" in the "Department of Regulatory and Quality Sciences" at the University of Southern California (*See* CV of Susan Bain ("Bain CV") at 2 (Ex. A to Bain Rep.)), she does "not teach anything related to the actual manufacturing process of APIs" (Bain Dep. 114:9-14). Dr. Bain also testified that she had very few interactions with the FDA over the last 20 years, despite repeated claims stating otherwise on her resume. For example, although Dr. Bain's resume lists multiple purported examples of her working with the FDA (*see* Bain CV), she estimated that her direct contact with the agency itself amounted to "three calls" totaling "less than 30 minutes" and a few other interactions of which she could not recall the specifics (*see* Bain Dep. 31:4-34:9). Additionally, Dr. Bain could not recall any company she worked at ever "receiving a 483" or "warning letter" from the FDA while she was there (Bain Dep. 21:8-20),

despite claiming on her resume that she "[c]oordinated, prepared, and revised responses" to such letters while working at Watson (*see* Bain CV).

Dr. Bain is admittedly "not an organic chemist" and does not "think [she is] qualified to offer an opinion on how nitrosamines form." (Bain Dep. 79:11-17; *see also, e.g.*, *id.* 85:16-86:1, 102:1-6.) She has never "taught a course in organic chemistry" (*id.* 25:7-9), and the only course she has taken in organic chemistry was "during [her] undergrad" education in the mid-1970s (*id.* 25:10-23). Dr. Bain's resume similarly does not suggest that she has any experience in the fields of organic chemistry or nitrosamine formation. (*See* Bain CV.) Given her lack of experience in that area, Dr. Bain relied almost exclusively on "Dr. [Stephen] Hecht's and [Ron] Najafi's reports" and "some of the literature" cited therein in forming her science-based opinions. (Bain Dep. 125:5-126:14; *see also, e.g.*, *id.* 79:18-80:6, 81:16-82:12, 84:8-17, 102:1-11, 111:17-23.)

ARGUMENT

The standards governing the admissibility of expert testimony are set forth in Defendants' Memorandum of Law in Support of Motion to Exclude Opinions of Dr. Laura M. Plunkett, and incorporated fully herein. All of Dr. Bain's opinions should be excluded under those standards.

I. DR. BAIN IS NOT QUALIFIED TO SERVE AS AN EXPERT IN THIS CASE.

"Before an expert witness may offer an opinion pursuant to Rule 702, [s]he must first be qualified by virtue of specialized expertise." *Ortiz v. Yale Materials Handling Corp.*, No. 03-3657FLW, 2005 WL 2044923, at *3 (D.N.J. Aug. 24, 2005) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)). "If an expert's area of experience 'is adjacent to, but not actually encompassing, the subject matter of h[er] testimony, [s]he may be deemed unqualified.'" *D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. Civ.A. 03-1026(MLC), 2006 WL 755984, at *3 (D.N.J. Mar. 20, 2006) (citation omitted). An "expert's" inability to correctly answer basic questions and explain her opinions at her deposition is a telltale sign that the witness "is not competent to offer testimony to the jury on such matters." *Dreyer v. Ryder Auto. Carrier Grp., Inc.*, 367 F. Supp. 2d 413, 428 (W.D.N.Y. 2005) ("Proctor's inability to explain, within the relatively flexible confines of a pretrial deposition of a proposed expert witness, how the good engineering practices referred to by Proctor would be applied" to the facts of the case "demonstrates Proctor lacks competency to assist the jury in understanding

the issues.").[1] Dr. Bain's regulatory and science-based opinions are inadmissible under these standards.

A. Dr. Bain Is Not Qualified To Offer Her Regulatory Opinions.

1. Dr. Bain lacks the requisite experience to serve as a regulatory expert in this case.

Courts routinely exclude regulatory opinions where experts are not qualified to opine on the specific regulatory scheme at issue in a case. *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 2:12-cv-07263, 2016 WL 4538621, at *8 (E.D. Pa. Aug. 31, 2016) (excluding opinions of regulatory expert on "the regulatory framework of the NDA or monograph system because she [was] not an expert in this area"); *Ghorley v. Baxter Healthcare Corp.*, No. 1:17-cv-3091-TCB, 2019 WL 13240522, at *6 (N.D. Ga. Sept. 9, 2019) (excluding expert's opinions on "medical device regulation" where his only FDA experience was in pharmaceuticals).

[1] *See also, e.g., United States v. Arrow-Med Ambulance, Inc.*, No. 17-CR-73-JMH, 2018 WL 1902682, at *4 (E.D. Ky. Apr. 20, 2018) ("Dr. Russell is not qualified to testify as an expert on Medicare regulations, particularly when he does not accurately state those regulations."); *Mancuso v. Consol. Edison Co.*, 967 F. Supp. 1437, 1443-44 (S.D.N.Y. 1997) (finding expert unqualified to offer toxicological causation opinions where, "despite his testimony that he had read 40 or 50 articles over the course of fifteen years before authoring his initial opinion, and that he subsequently performed approximately 14-15 hours of library research and review before authoring his supplemental opinion and appearing for his deposition, [the expert] was unable to answer critical questions regarding PCBs" at his deposition) (citation omitted).

For example, in *Ghorley*, the plaintiff offered a regulatory expert to opine, *inter alia*, on "compliance by [defendant] with respect to the [cGMPs] and other applicable [FDA] standards regarding" an allegedly defective medical device. *Ghorley*, 2019 WL 13240522, at *5. Although the expert did have significant "work experience at the FDA" from his ten-year experience with the agency, he "worked for the Center for Drug Evaluation and Research, not the Center for Devices." *Id.* The court agreed with defendants that the expert's time "at the FDA working with ***pharmaceuticals*** d[id] not make him an expert on labeling medical ***devices***" and therefore excluded his opinions. *Id.* at *6 (emphases added).

Dr. Bain's FDA experience is even less extensive and more attenuated to this case than the experience the *Ghorley* court deemed insufficient. Although Dr. Bain may have garnered some experience in the realm of device and veterinary drug regulations, her very short stint at the FDA at the beginning of her career did not provide her with any experience regarding the regulations governing API manufacturers, or even human pharmaceuticals in general. As she readily admitted, Dr. Bain never worked on drugs meant for human consumption while at the FDA (Bain Dep. 16:1-3); never "evaluate[d] cGMP compliance by manufacturers of finished drug products for humans" (*id.* 114:5-8); never conducted "any inspections of API manufacturers" (*id.* 113:20-25; *see also id.* 16:9-11); and never reviewed a Drug Master File (*see id.* 16:4-6) or an ANDA (*see*

id. 16:7-8). Dr. Bain's experience as an FDA consultant over the last 12 years is likewise irrelevant because "about 70 percent of [her] clients have been medical device" manufacturers, and ***none*** of the remaining 30 percent are "API manufacturers." (*Id.* 226:16-227:4.) In short, as Dr. Bain conceded, her "expertise is ***not*** in the area of API" manufacturers. (*Id.* 120:3-11 (emphasis added).)

Even more troubling, although Dr. Bain's resume repeatedly touts examples of regulatory work and interactions with the FDA, including while she was employed at a generic pharmaceutical manufacturer (*see* Bain CV), those experiences appear to have been fabricated. For example:

- Dr. Bain represents on her resume that she "[c]oordinated, prepared, and reviewed responses to deficiency letters" while working at Watson (Bain CV at 4), but she testified at her deposition that she actually "wasn't part of that" (Bain Dep. 19:12-14). In fact, Dr. Bain could not recall "any company" she worked at "receiving a 483" or "warning letter" from the FDA while she was working there. (Bain Dep. 21:8-20.)

- Dr. Bain states on her resume that she maintained a "working . . . interface" with the FDA regarding recalls while at Watson. (Bain CV at 4.) But at her deposition, Dr. Bain testified that she has never "had a role in any company in which [she was] responsible for communicat[ions] with the FDA about product recalls" (Bain Dep. 20:16-19), and that she never had "any interaction with [the] FDA at Watson" (*id.* 26:16-18; *see also, e.g., id.* 39:14-16).

- Dr. Bain claims on her resume that she "[r]eported . . . Adverse Events to the FDA as required" in her role as a Director of Quality Assurance/Quality Control while at Techniclone Corporation (Bain CV at 5), but she testified at her deposition that she was not "responsible for reporting adverse events to the FDA" while in that position (Bain Dep. 39:11-13).

- Dr. Bain claims on her resume to have "[r]epresented QC Dept. during on-site FDA . . . inspections" at Alpha Therapeutic Corporation (Bain CV at 6), but at her deposition, she could not recall ever actually doing so (*see* Bain Dep. 39:1-10).

- Finally, although Dr. Bain claims on her resume to have had numerous interactions with the FDA during her private sector career, she could only remember ever having a ***mere three calls lasting less than 30 minutes total*** with the FDA over the last two decades. (*See* Bain Dep. 31:4-34:9.)

For these reasons alone, her regulatory opinions should be excluded from trial.

2. Dr. Bain demonstrated a lack of basic regulatory competency at her deposition.

Given Dr. Bain's lack of relevant regulatory experience, it is no surprise that she was unable at her deposition to correctly answer even the most basic questions about the regulatory framework underlying her opinions. This only confirms that Dr. Bain "is not competent to offer testimony to the jury on such matters." *Dreyer*, 367 F. Supp. 2d at 428.[2]

ICH guidelines. Dr. Bain claims that ZHP's alleged failure to properly follow guidance issued by the International Council for Harmonization ("ICH") resulted in violations of cGMPs. (*See, e.g.*, Bain Rep. at 1-2, 15, 62.) Although Dr. Bain believes that this guidance "establish[es] . . . legally enforceable

[2] Dr. Bain also did not know basic facts of the underlying litigation, erroneously stating that ZHP is the plaintiff in this case. (*See* Bain Dep. 12:3-4.)

responsibilities" (Bain Dep. 149:2-6), the FDA has made clear that ICH guidelines do "not establish legally enforceable responsibilities"[3] – i.e., they "do not legally bind the public or FDA," 21 C.F.R. § 10.115(d)(1). And Dr. Bain's testimony that she "disagree[s]" with the FDA's reasoned judgment on the subject (Bain Dep. 149:6) cannot be credited, because she has no experience or knowledge that qualifies her to challenge the FDA's pronouncements on how ***it views*** the import of ICH guidelines.

Dr. Bain also has no understanding of what those guidelines actually say, much less what they mean for API manufacturers such as ZHP. For example, Dr. Bain testified based on her "background and training" that "ICH Q8 applies to API" development and "broadly discusses product development." (Bain Dep. 157:2-158:10.) But that guideline only "describes the suggested contents for the 3.2.P.2 (Pharmaceutical Development) section of a regulatory submission," not the pharmaceutical development process itself.[4] Similarly, Dr. Bain erroneously

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[3] FDA Q8(R2) § 1.1, https://www.fda.gov/media/71535/download; *see also, e.g.*, FDA Q9 § 1, https://www.fda.gov/media/71543/download (same); FDA Q10 § 1.1, https://database.ich.org/sites/default/files/Q10%20Guideline.pdf ("ICH Q10 is not intended to create any new expectations beyond current regulatory requirements.").

[4] FDA Q8(R2) § 1.1 (emphasis added); *compare id.* § 1.1 ("The Q8 parent guidance ***describes the suggested contents*** for the 3.2.P.2 (Pharmaceutical Development) section of a regulatory submission") (emphasis added), *with* ICH Q11 § 1, https://www.fda.gov/files/drugs/published/Q11-Development-and-
(cont'd)

testified that "ICH Q9" addresses "[q]uality systems" (Bain Dep. 159:7-15), even though, as her report explains, that topic is actually addressed by ICH Q10 (*see* Bain Rep. at 4).

Dr. Bain was also confused at her deposition about ZHP's purported obligations to identify unknown peaks on chromatography when testing for impurities in Valsartan API. Dr. Bain apparently believes that ZHP was required to "investigate ***all*** unknown peaks" of impurities regardless of their levels (*see* Bain Dep. 164:17-165:1 (emphasis added)), and that ZHP would have committed a cGMP violation if it tried and failed to identify ***any*** unknown peaks (*see id.* 141:9-23). But ICH Q3A and Attachment 1 to the FDA guidance on Q3A – both of which are listed on Dr. Bain's reliance list (*see* Bain Rep. at 4 & Ex. B) – expressly state that manufacturers have ***no*** obligation to identify unknown peaks below a threshold of 0.10% of the maximum daily dose of a drug.[5] Dr. Bain was apparently unaware of that fact. (*See* Bain Dep. 166:22-168:1.) Relatedly, Dr. Bain testified that "Valsartan [with] impurities at any level whatsoever, that were

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Manufacture-of-Drug-Substances.pdf ("This guidance describes approaches to developing and ***understanding the manufacturing process*** of the drug substance, and also provides guidance on what information should be provided in Module 3 of the Common Technical Document (CTD) sections 3.2.S.2.2 – 3.2.S.2.6.") (emphasis added).

[5] ICH Q3A(R2) at 8, https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf; ICH Q3A Attach. 1, https://www.fda.gov/media/71727/download.

not found in Diovan" (the reference listed drug) "would not meet [the] Diovan USP" (*id.* 207:18-210:12.) But the general guidelines for USPs explicitly state that "[t]he presence of any unlabeled other impurity in an official substance is a variance from the standard ***if*** the content is 0.1% or greater,"[6] meaning that Valsartan API with impurities beneath that level would, in fact, satisfy the Diovan USP. With no background on these issues, it is no surprise that Dr. Bain did not know these basic principles.

FDA regulations. Dr. Bain also did not accurately testify about the general regulatory materials that she allegedly reviewed in relation to this case. Although Dr. Bain testified that 21 C.F.R. § 210.1(a) and 21 C.F.R. § 211(b) apply to API manufacturers (*see* Bain Dep. 142:6-12), the regulations themselves make clear that these sections apply only to finished dose manufacturers, *see* 21 C.F.R. § 210.3(b)(4) ("Drug product means a finished dosage form . . . ."); 21 C.F.R. § 211(a) ("The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products . . . ."). Dr. Bain similarly displayed a lack of basic knowledge of the FDA itself, stating that she did not know whether the FDA employs organic chemists, has a Department of Chemistry and relies on trained chemists to review Drug Master Files in connection with

[6] USP 32 § 5.60.10, https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalNoticesandRequirementsFinal.pdf (emphasis added).

ANDAs (*see* Bain Dep. 103:21-104:11) – the very materials that Dr. Bain attempts to criticize in her report (*see* Bain Rep. at 24-26). Similarly, while Dr. Bain contends that ZHP violated FDA regulations, she was entirely unaware of what (if any) regulatory actions the FDA took with respect to ZHP's VCDs prior to 2018. (*See* Bain Dep. 173:7-174:14.)

Dr. Bain's fundamental lack of knowledge about FDA regulations and agency action renders her even less qualified to opine on U.S. legal requirements than one of plaintiffs' class-certification experts, whom this Court previously excluded in part because "U.S. codes and regulations" are "more legally nuanced than Mr. Quick is qualified to opine on." (*See* Ops. on Certification of Proposed Classes under FRCP Rule 23 and on Class Certification Expert Reports under FRE 702 ("Class Certification Ruling") at 93, ECF No. 2261).)[7]

In short, not only is Dr. Bain's limited regulatory experience "adjacent to" her opinions in this case, *D & D Assocs.*, 2006 WL 755984, at *3 (citation omitted), but she also could not answer basic questions regarding the regulations

[7] Dr. Bain also could not answer the most basic questions about materials listed on her reliance list. For example, Dr. Bain claimed to have read the report of ZHP's regulatory expert Dr. Ali Afnan, but then had no idea who he was, guessing after a pause that he was "an expert in the field of nitrosamines" (Bain Dep. 215:18-23), despite having disclosed his report on her supplemental reliance list just two days before her deposition (*see* Ex. 2 to Bain Dep. (Ex. 3 to Davidson Cert.)).

and guidance that underlie her report, demonstrating that she "is not competent to offer testimony to the jury on such matters," *Dreyer*, 367 F. Supp. 2d at 428.

B. Dr. Bain Is Not Qualified To Offer Her Science-Based Opinions.

Dr. Bain's opinions about ZHP's manufacturing processes implicate complex questions related to organic chemistry that she is even less qualified to discuss, which is presumably why she resorted to simply parroting the conclusions of plaintiffs' other experts.

1. Dr. Bain lacks the experience and knowledge to opine about chemical reactions.

The gist of Dr. Bain's science-based opinions is that the chemical reactions that supposedly form NDMA and NDEA in ZHP's TEA with sodium nitrite quenching and zinc chloride manufacturing processes "were known and available" prior to 2018, when the FDA first issued guidance on testing for these compounds. (Bain Rep. at 31.) In particular, Dr. Bain devotes large swaths of her report to elaborating on those two manufacturing processes (*see, e.g.*, *id.* at 19-24), and then asserting that ZHP violated cGMPs in connection with both of those processes (*see, e.g.*, *id.* at 69-74). However, it is beyond dispute that Dr. Bain does not have the experience or training necessary to opine on ZHP's manufacturing processes, including the purported risks they pose and what testing ZHP should have employed in connection with those processes. Dr. Bain readily testified that she is "not an organic chemist" and, thus, does not "think [she is] qualified to offer an

opinion on how nitrosamines form." (Bain Dep. 79:11-17; *see also, e.g.*, *id.* 85:16-86:1, 102:1-6.) The only remotely relevant training she appears to have in the field of organic chemistry is a single "introductory" course she took 50 years ago, in which she does not recall ever learning "anything about nitrosamines." (*Id.* 25:7-26:1.) This "string of admissions by [Dr. Bain] that [s]he is unqualified to opine on" issues of organic chemistry suffices to show that she does not have the requisite qualifications to offer opinions on the relevant manufacturing processes. *Ely v. Cabot Oil & Gas Corp.*, No. 3:09-CV-2284, 2016 WL 4169220, at *6 (M.D. Pa. Feb. 17, 2016).

Moreover, Dr. Bain could not answer basic questions at her deposition about the two valsartan API manufacturing processes and methodologies for testing drug products for impurities. *See Dreyer*, 367 F. Supp. 2d at 428 (finding that an "expert who is incapable of explaining forthrightly basic concepts within his claimed area of expertise . . . at a deposition is not competent to offer testimony to the jury on such matters"). Most notably, when asked to differentiate between the two processes, Dr. Bain's response was that "I have to go back and look to make sure." (Bain Dep. 185:15-18.) Similarly, although Dr. Bain opines in her report that ZHP should have used a gas chromatography-mass spectrometry method to test for NDMA in Valsartan (*see* Bain Rep. at 72), Dr. Bain could not explain the difference between that testing methodology and the gas chromatography flame

ionization detector ("GCFID") method that ZHP employed prior to 2018 (*see* Bain Dep. 102:20-103:20). Nor could Dr. Bain explain why the GCFID method is not always capable of detecting NDMA (*see* Bain Dep. 103:18-20), or what exactly ZHP did in its risk assessments with regard to its manufacturing processes (*see id.* 178:19-179:2).

Dr. Bain was unable to answer questions related to her report even after being led by plaintiffs' counsel to agree to paragraphs he read into the record. For example, although plaintiffs' counsel repeatedly referred to "high-potency genotoxic N-Nitroso compounds" and "no genotoxic risk" in quoting from Dr. Bain's report and leading Dr. Bain to state that ZHP did not undertake adequate risk assessments (*see* Bain Dep. 239:19-240:10), Dr. Bain stated that she does not know what the difference is between the two terms and could not differentiate between them (*see id.* 247:22-251:11). Similarly, after plaintiffs' counsel read from a July 27, 2017 ZHP email regarding the drug Irbesartan and led Dr. Bain to "agree" that the presence of NDMA in that medication "would be a serious [c]GMP problem" (*id.* 245:15-19), Dr. Bain stated that she "d[oes not] know" whether Irbesartan is "the same molecule as Valsartan or a different molecule" (*id.* 253:15-17).

When plaintiffs' counsel was not reading portions of Dr. Bain's report into the record, he quoted from other documents Dr. Bain allegedly had reviewed. For

example, plaintiffs' counsel quoted from a document that states that "DMF sold commercially contains trace amounts of . . . dimethylamine" and then asked Dr. Bain, based on that document, "[s]hould ZHP have been aware that the DMF could come through the door with dimethylamine" – regardless of any degradation. (*See* Bain Dep. 236:10-24, 237:6-11; *see also id.* 132:16-133:14.) But when questioned by defense counsel on this claim, Dr. Bain testified that she has "no idea" whether "a reasonable chemist would" have tested commercially sold DMF for dimethylamine. (*See id.* 247:17-21.)[8] In sum, Dr. Bain "was unable to answer critical questions" regarding her opinions, *Mancuso*, 967 F. Supp. at 1443-44, even after being pointed to the relevant portions of her report by plaintiffs' counsel, reinforcing her lack of competency to weigh in (much less offer "expert" testimony) on these matters.

2. Dr. Bain inappropriately parrots the conclusions of plaintiffs' other experts.

Although an expert may rely upon another expert's opinion in formulating her own views, an "[e]xpert[] may not simply 'parrot' the ideas of other experts and should not 'become the mouthpiece of the witness on whose statements the expert

[8] This opinion is doubly improper because it was not previously disclosed in Dr. Bain's report; rather, plaintiffs' counsel improperly led the witness into giving an entirely new opinion, in contravention of Federal Rule of Civil Procedure 26. *See Krys v. Aaron*, 112 F. Supp. 3d 181, 207 (D.N.J. 2015) (precluding testimony because "it is axiomatic that an expert may not present new opinions on topics not timely included or otherwise disclosed in the expert's report").

purports to base his opinion.'" *Torain v. City of Philadelphia*, No. 14-1643, 2023 WL 174952, at *5 (E.D. Pa. Jan. 12, 2023) (citation omitted); *see also Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612-14 (7th Cir. 2002) (stating that an expert "is not permitted to be the mouthpiece of a scientist in a different specialty"). This is so because Federal Rule of Evidence 703 "contemplates that a testifying expert can 'validate the facts, data and opinions he relied upon . . . and be subject to cross-examination on them.'" *Muhsin v. Pac. Cycle, Inc.*, No. 2010-060, 2012 WL 2062396, at *4, *8 (D.V.I. June 8, 2012) (citation omitted).

Dr. Bain is seeking to serve as a "mouthpiece" for the science-based opinions of two other experts in this litigation, Drs. Hecht and Najafi. When questioned about her opinions that the purported NDMA- and NDEA-related risks posed by ZHP's manufacturing processes were "known and available" prior to 2018, Dr. Bain repeatedly responded that they are "[b]ased on the reports of . . . Drs. Hecht and Najafi" – which she did not "personally test." (Bain Dep. 82:1-12; *see also, e.g., id.* 79:24-80:6 (invoking "Dr. Hecht's report, and Dr. Najafi['s]"); *id.* 82:1-4 ("Based on the reports of . . . Drs. Hecht and Najafi, it's my feeling that this reaction is something that is covered or well understood in the organic chemistry field."); *id.* 84:8-17 (similar); *id.* 85:1-9 (testifying that her opinion that organic chemists knew in 2011 that DMF could degrade below the boiling point is "based on Dr. Hecht and Dr. Najafi"); *id.* 102:10-11 (testifying that she is "relying on Dr.

Hecht's and Najafi's reports" in opining that it is easy to find NDMA and NDEA in VCDs).)

Although Dr. Bain also claimed that she "read the literature cite[d]" by Drs. Hecht and Najafi, the only specific literature Dr. Bain could point to was the 1978 International Agency For Research On Cancer monograph ("IARC monograph"), which she asserts "stat[es] that DMF can degrade into [dimethylamine] in the same conditions that are present in ZHP's manufacturing process for Valsartan." (*See, e.g.*, Bain Dep. 130:25-131:4; *see also, e.g., id.* 79:24-80:11, 84:8-21, 129:2-131:11, 132:3-5.) However, the IARC monograph does not say anything about DMF degrading into dimethylamine, much less doing so under the same conditions that are present in ZHP's manufacturing process. Rather, it merely addresses the unremarkable potential for dimethylamine ***itself*** to form nitrosamines.[9] Moreover, to the extent certain literature relied upon by Drs. Hecht and Najafi does address the potential for DMF to degrade into dimethylamine, it makes clear that such degradation can only occur when DMF reaches its boiling point (i.e., in excess of 350 degrees) (*see* Bain Dep. 136:12-15) – a critical circumstance Dr. Bain could

[9] *See* International Agency For Research On Cancer, *IARC Monographs On The Evaluation Of The Carcinogenic Risk Of Chemicals To Humans: Some* N-*Nitroso Compounds* (May 1978).

not say occurred in ZHP's manufacturing process. (*See id.* 130:25-131:18, 246:8-13.)

In short, as with Dr. Bain's regulatory opinions, her science-based opinions are not the product of any relevant expertise or knowledge and, if admitted at trial, would simply bolster the opinions of plaintiffs' other experts without adding any expertise of her own.

II. DR. BAIN'S OPINIONS ARE NOT BASED ON A RELIABLE METHODOLOGY AND DO NOT CONSTITUTE PROPER EXPERT EVIDENCE.

Even if Dr. Bain were qualified to offer opinions on the regulatory and science-based matters set forth in her report, many of her opinions would still be inadmissible because they are not based on any (much less a reliable) methodology; they consist of improper legal conclusions that usurp the role of the Court and the jury; and they summarize deposition and other factual materials that a lay jury is capable of understanding for itself.

A. Dr. Bain's Opinions Are Not Based On A Reliable Methodology.

Experts must "explain precisely how they went about reaching their conclusions and point to some objective source . . . to show that they have followed the scientific method." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995). As this Court explained at the class-certification stage, an expert has "stated no method" where he does "not detail what documents he has

reviewed, why he reviewed them, what his search query was, and why he excluded other documents." (Class Certification Ruling at 84.) Dr. Bain lacked any method because she admitted that all of the documents discussed in her report were provided to her by plaintiffs' counsel, rather than acquired in the course of her own independent research. (*See* Bain Dep. 219:15-23.) *See also Kremsky v. Kremsky*, No. 16-4474, 2017 WL 663091, at *2 (E.D. Pa. Feb. 17, 2017) ("An expert's opinion does not rest on good grounds where he simply relies on the data provided by his client without independent verification.").

For example, Dr. Bain did not even inquire about – or evaluate – any audits by ZHP's customers of the company's manufacturing processes prior to 2018, including one by Novartis finding that ZHP had an adequate quality system in accordance with applicable ICH guidelines. (*See, e.g.*, Bain Dep. 175:16-24, 177:7-21; ZHP02450736 at -738 (Ex. 4 to Davidson Cert.).) Nor did she include portions of fact deposition testimony in her report (e.g., sections of Dr. Eric Gu's testimony regarding ZHP's good-faith efforts to follow all ICH and cGMP guidelines) that undercut her opinions. (*See* Bain Dep. 155:21-157:1; *see also id.* 155:4-20 (testifying that she did not address these relevant parts of Dr. Gu's testimony in her report).) Notably, plaintiffs' counsel would not even permit Dr. Bain to explain how she decided what deposition testimony to include in her report

(*see* Bain Dep. 63:20-23), raising serious questions as to what (if any) role Dr. Bain had in formulating her purported opinions.

Dr. Bain's report also generated illogical and unreliable opinions. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017) ("Both an expert's methodology and the application of that methodology must be reviewed for reliability."). For example, Dr. Bain seeks to opine that ZHP's risk assessments were deficient because they did not uncover the presence of NDMA or NDEA (*see* Bain Dep. 169:7-12), rather than criticizing the actual steps of the risk assessments themselves (which she obviously would have no idea how to do). Such "circular reasoning fails to reveal a sufficiently rigorous analytical connection between [Dr. Bain's] methodology and h[er] opinion." *Bocoum v. Daimler Trucks N. Am. LLC*, No. 17 Civ. 7636 (JPC) (BCM), 2022 WL 902465, at *11 (S.D.N.Y. Mar. 28, 2022) (citation omitted) (excluding opinion that a certain part in a vehicle must have been structurally compromised prior to a crash where the only basis for the expert's assertion was the fact that the part was discovered fractured following the crash); *see also, e.g.*, *Daniels v. Grand Lux Cafe, LLC*, No. 12-7848 (JEI/KMW), 2015 WL 1398325, at *7 (D.N.J. Mar. 26, 2015) (excluding opinion regarding adequacy of corporate policies because it rested on circular logic – that the policies were inadequate because the policies

were violated, which was "not a sound foundation"). For this reason, too, Dr. Bain's opinions should be excluded.

B. Many Of Dr. Bain's Opinions Are Improper Legal Conclusions.

Dr. Bain should also be prohibited from offering legal conclusions because "experts generally may not testify to what the law *requires* or whether a party *complied* with the law . . . ." *Moorestown Twp. Bd. of Educ. v. S.D.*, No. 10-0312 (RMB), 2010 WL 4062182, at *5 (D.N.J. Oct. 15, 2010); *see also Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) ("[A]n expert witness is prohibited from rendering a legal opinion . . . ."). Consistent with this principle, courts have refused to allow experts to offer opinions on a pharmaceutical company's compliance with applicable regulations. *See, e.g.*, *Stanley v. Novartis Pharms. Corp.*, No. 11-03191 JGB (OPx), 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014) (precluding an expert from "offer[ing] legal conclusions, including whether [d]efendant was in regulatory compliance with the FDA"); *In re Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prods. Liab. Litig.*, MDL No. 2436, 2016 U.S. Dist. LEXIS 98858, at *8-9 (E.D. Pa. July 27, 2016) (excluding expert opinion regarding whether a drug met a certain standard pursuant to FDA regulations, as such an opinion "would require a legal interpretation" of that standard); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (holding that opinions regarding "the duties of pharmaceutical companies

are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert"). Indeed, in its Class Certification Ruling, this Court excluded Dr. Najafi's Class Certification Report on the basis that "the subject matter of Dr. Najafi's opinions [in his Class Certification Report], about what is bioequivalence, wades too far into the factfinder's domain." (Class Certification Ruling at 91.)

Much of Dr. Bain's report violates these well-established principles by interpreting statutory and regulatory requirements for pharmaceutical manufacturers and then asserting that ZHP "violated" those legal obligations. (*See, e.g.*, Bain Rep. at 1 (ZHP "violated [c]GMPs (e.g., 21 CFR § 210(a); 21 CFR § 211(b)")); *id.* at 2 (the product was adulterated "within the meaning of section 501(a)(2)(B) of the [FDCA]"); *id.* at 5 (setting forth overview of FDCA and regulatory requirements).) These opinions inappropriately usurp the role of the Court to instruct the jury on the meaning of the applicable law and the role of the jury to determine whether ZHP violated that law.

C. Dr. Bain's Factual Narratives Are Also Improper.

Finally, Dr. Bain's opinions also do not constitute proper expert testimony to the extent they are based on a review of documents and testimony that jurors are equally capable of assessing. *See, e.g.*, *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 441-42 (D.N.J. 2009) (explaining that experts

may not "simply summarize the facts and the depositions of others"; "to the extent that [an expert's] testimony reflected no more than his summary of, and spin on, internal GEH documents, the [c]ourt finds that such testimony is unhelpful to the [c]ourt as the trier of fact and excludes such testimony from the record") (quoting *Crowley v. Chait*, 322 F. Supp. 2d 530, 553 (D.N.J. 2004)). This is so because plaintiffs' factual case should be "presented through introduction of documents or non-expert testimony," and not expert testimony that simply "regurgitat[es] factual information" with the false imprimatur of some special knowledge on the subject. *Pritchett v. I-Flow Corp.*, No. 09-cv-02433-WJM-KLM, 2012 WL 1059948, at *7 (D. Colo. Mar. 28, 2012).

Large swaths of Dr. Bain's report simply "regurgitat[e] factual information" and package it as expert opinion. In a nearly 30-page section titled "Deposition Testimony," Dr. Bain quotes at length from various internal company documents and prior testimony that any lay juror could easily understand for him or herself. (*See* Bain Rep. at 26-57.) Even assuming Dr. Bain had articulated a methodology for her deposition summaries (i.e., how and why certain testimony was included, while other evidence was not), jurors are more than capable of comprehending the statements of fact witnesses, particularly given that Dr. Bain does not apply relevant expertise to interpreting the testimony. Rather, it appears quite likely based on her deposition testimony that the summaries were prepared by attorneys,

although plaintiffs' counsel refused to permit Dr. Bain to answer whether she "wr[o]te" them. (Bain Dep. 63:8-10.) For this reason, too, Dr. Bain's opinions are improper and inadmissible and should be excluded.

CONCLUSION

For the foregoing reasons, the Court should exclude all of Dr. Bain's opinions in full.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 13, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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